

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLÉGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

# Aloxi

palonosetron HCl injection

Content [1/5/2004]

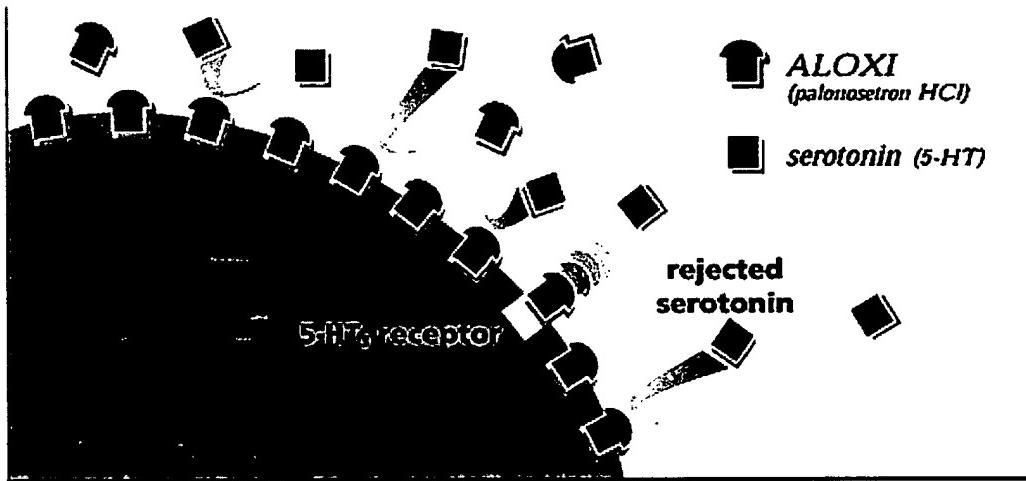
## Binding Affinity

### NEW ALOXI™ BINDS STRONG, LASTS LONG.

#### HIGHLY SELECTIVE FOR THE 5-HT<sub>3</sub> RECEPTOR.<sup>1</sup>

- A receptor binding affinity at least 30X higher than any other 5-HT<sub>3</sub> receptor antagonist.<sup>†1,2</sup>
- A highly selective 5-HT<sub>3</sub> receptor antagonist, with little or no affinity for other receptors.<sup>1,3</sup>

#### RECEPTOR BINDING AFFINITY<sup>1</sup>



<sup>†</sup>In vitro

*data; clinical significance has not been established.*

Aloxi is contraindicated in patients known to have hypersensitivity to the drug or any of its components. It should be administered with caution in patients who have or may develop prolongation of cardiac conduction intervals, particularly QTc. Most commonly reported adverse reactions include headache (9%) and constipation (5%).

#### References

1. Wong EHF, Clark R, Leung E, et al. The interaction of RS 25259-197, a potent and selective antagonist, with 5-HT<sub>3</sub> receptors, *In vitro*. *Br J Pharmacol.* 1995;114:851-859.
2. Miller RC, Galvan M, Giltos MW, van Giersbergen PLM, Moser PC, Fozard JR. Pharmacological properties of dolasetron, a potent and selective antagonist at 5-HT<sub>3</sub> receptors. *Drug Dev Res.* 1993;28:87-93.
3. Aloxi™ (palonosetron HCl) injection full prescribing information.

Distributed and marketed by MGI PHARMA, INC., Bloomington MN 55437  
under license of Helsinn Healthcare SA, Switzerland.  
©2003 MGI PHARMA, INC., Bloomington, MN 55437 U.S.A.